

# Business Process Evaluation and Improvement Tool for Inspection Systems

A Partnership for Food Protection Resource Document



Information Technology Workgroup

Business Process Evaluation and Improvement Tool for Inspection Systems

This tool was created by the 2011-2012 Partnership for Food Protection (PFP) Information Technology (IT) Workgroup. In 2014, the Record Management section was revised to include additional elements related to privacy. The PFP IT Workgroup is composed of Federal, State, and Local regulatory representatives who work together to understand and define the requirements of developing an integrated electronic information management backbone, and undertake technical projects that align with findings and contribute to the creation of an national interoperable and integrated food safety system (IFSS).

#### Introduction

This tool was designed to address a common need present in many Federal, State, and Local regulatory programs. The tool is designed to help state and local programs gain a more detailed understanding of their program's business processes related to inspections, identify improvements, and serve as a mechanism to form requirements for IT system improvements or new developments. To gain the understanding of business processes, the tool walks regulatory program managers through nine core areas of their inspection program: inventory and licensing, assignments and scheduling, field work and inspections, recording of findings, issuance, review and approval, compliance and enforcement, record creation and retention, and data management.

Core Area # 1: Inventory and Licensing

Core Area # 2: Assignments and Scheduling

Core Area # 3: Field Work and Inspections

Core Area # 4: Recording of Findings

Core Area # 5: Issuance

Core Area # 6: Review and Approval

Core Area # 7: Compliance and Enforcement

Core Area # 8: Record Creation and Retention

Core Area # 9: <u>Data Management</u>

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#### **Instructions**

- 1. Assemble a cross-cutting taskforce to help complete the tool. Make sure to include staff from management, inspections, and support.
- 2. Complete the tool, but take your time. Be as thorough and as detailed as possible. Recognize any pre-conceived notions and attempt to approach this process with an open mind. Proper completion of the tool will take several sessions. When completing it for the first time, answer the questions in context of where your agency "currently is". You can then elect to complete the tool a second time, answering the questions in context of where your agency "wants to be".
- 3. Review your responses to the tool, specifically, looking for areas of improvement. The improvements you identify might encompass both changes to your business operations and the development of new IT tools.
- 4. Prioritize the gaps or areas of improvement based upon need and budget.
- 5. Provide the completed tool to potential IT developers or department program managers as a resource for developing IT or business process improvements.

#### **TIP**: Read through all material before getting started!

**TIP:** Create a parking lot for ideas that arise during the process but don't specifically address a question.

**TIP:** When you document an action taken during any of these processes, think about if the actions trigger/flag another aspect/component of your system?

#### Characteristics of Agency, Division, and Programs

- 1. Identify your agency and division and the responsibility/mission of each.
- 2. Outline the internal structure of your division/organization, including the primary program areas within your division.
- 3. Do you have documented business processes or Standard Operating Procedures (SOP)? If so, describe them. Are the SOPs accurate and up to date? If not, consider developing a documented business process as an aid in this review process.



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- 4. For each of the primary program areas identified in question 2:
  - a. What are the responsibilities of each program area? What do they accomplish?
  - b. What are the job roles within each program area (e.g. secretary, inspector, data entry, administrator, etc.)?
  - c. For each job role identified in question 4b:
    - 1. Describe the type of workload, the volume, and how they might be inter-related.
    - 2. How many people are within each job role?
    - 3. Where are the people located (e.g. field, office, etc.)?
  - d. Which program areas communicate with each other/need to exchange information?

**TIP:** If your organization has documented business processes or SOPs, reference them in answering this section.

**TIP:** First think of roles and responsibilities used to accomplish every day work. Secondly, think of roles and responsibilities used to respond during emergencies.

**TIP:** Think about how your program accomplishes specific tasks. Who is involved? What do they do? Who do they receive information from or give information to?

- 5. List partners and other agencies your division/organization regularly communicates with.
  - a. What information is communicated to each?
  - b. What is the frequency?
  - c. How timely does the information need to be?
- 6. What is the most common equipment used currently to manage the roles and responsibilities within your program?

The next sections of this tool will more closely examine the requirements for an inspection system. Though the questions will be focusing on the inspection process, it will touch upon other systems that could possibly interact with the inspection system (e.g. licensing, laboratory, training, compliance/enforcement, complaints, billing and collection, etc.)

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#### Core Area #1: Inventory and Licensing

Purpose: Regulatory program has an up-to-date listing of firms and locations; potentially serves as revenue stream for regulatory program.

1. How do you maintain a firm inventory?

**TIP:** In some agencies, this is also a licensing function. If your agency deals with licensing, it is recommended that you tie the firm inventory to the licensing if this has not been done already.

- 2. Are your licensing processes separate from your inventory processes?
- 3. Are your inventory processes reliant upon your licensing processes?
- 4. What information or data fields related to a firm do you collect? Identify field names and function.
  - a. Inventory Characteristics (firm name, firm alias, owner/operator, mailing address, physical address, size, etc.)
  - b. Licensing Information (license number, type of license, business mailing, issue/expiration date, etc.)
  - c. Firm Status (active/operational, inactive, expired, out of business, temporary, seasonal, etc.)
- 5. Do you use unique identifiers? If so,
  - a. What is the unique identifier associated with?

**TIP:** Do not forget to discuss how your program deals with corporations that might have multiple sites/locations.

b. What criteria require or trigger a new unique identifier?

**TIP:** For instance, does a change of address require a new unique identifier?

- c. How is the identifier created?
- d. Can the identifier be transferred? If so, explain the process.
- 6. In relation to the management of firms, describe how you:
  - a. Know that a new firm needs to be created.
    - 1. Where does the information come from?
  - b. Know when a firm needs to be updated.
    - 1. Where does the information come from?

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- c. Create a new record.
  - 1. What determines the need for a new record?
- d. Identify any existing automated processes for creating a new firm record.
  - 1. Do you rely on a separate IT system for data on new firms?
- e. Identify any existing manual processes for creating a new firm record.
- f. Update record inventory and licensing characteristics.
  - 1. For each field identified in question 6a-b, describe how the change is made and where the updated information came from.
- g. Update record status.
  - 1. For each field identified in question 6c describe how the change is made and where the updated information came from.
- h. Deal with duplicates.
  - 1. How do you avoid duplicates?
  - 2. How do you identify duplicates?
  - 3. How do you resolve duplicates?
  - 4. How could you improve your process for avoiding, identifying, and resolving duplicates?

**TIP:** Think about how you receive new firm information. Does an internal or external system establish your inventory? Does someone manually locate and add a new firm to the inventory? Where are the inputs?

- 7. Is your entire inventory licensed (go to question 7a) or is just a subset of the inventory licensed (go to question 7b)?
  - a. If you license all firms in inventory:
    - 1. How do firms submit license information?
    - 2. How do you process the license information?
    - 3. How do you currently distribute licenses?
      - i. What is the format?
      - ii. What is the distribution method?
      - iii. What is the time frame?
  - b. If you license only a sub-set:
    - 1. What firms are licensed?
    - 2. How do firms submit license information?
    - 3. How do you process the license information?
    - 4. How do you currently distribute licenses?
      - i. What is the format?

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- ii. What is the distribution method?
- iii. What is the time frame?
- c. If you do not issue licenses:
  - 1. Do you foresee issuing licenses in the future?

#### Core Area #2: Assignments and Scheduling

Purpose: Regulatory program assigns inspections to be completed.

- 1. Identify and list any legal requirements regarding inspection frequency.
- 2. Identify any contributing factors (criteria) and how they impact inspection frequency, assignments, and scheduling:
  - a. Inspector skill
  - b. Number of inspectors
  - c. Legal requirements
  - d. Geography
  - e. Specialized processing
  - f. Seasonality
  - g. Compliance/firm history
  - h. Contract work
  - i. Risk factors
  - j. Budget constraints
  - k. Other
- 3. Identify the types of inspections and how they impact assignments and scheduling:
  - a. Routine
  - b. Follow-up
  - c. Re-inspection
  - d. Compliance
  - e. Complaint
  - f. Contract
  - g. Other
- 4. Where does the information used to answer questions 1-3 reside?
  - a. How is each updated or changed?
  - b. Does data come from other systems or processes?

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5. How does an assignment get made? What is the process for delivering an assignment to an inspector?

**TIP:** How is this linked to your work planning process or inventory process?

- a. What information does an inspector need in an assignment for them to do their job?
  - 1. Firm inventory to inspector
  - 2. Priority list
  - 3. Firm history
  - 4. Complaints
  - 5. Compliance
  - 6. Risk assessment of firm
  - 7. Types of operations at the firm
  - 8. Due date
  - 9. Other
- b. Who makes assignments?
  - 1. Does a person or system generate and disseminate inspection assignments, or does the inspection staff access the inspection inventory and retrieve inspection assignments?
  - 2. Are the assignments made/selected individually or as a group?
  - 3. If assignments are incorporated into a schedule, how often is the schedule generated?
- c. Is the assignment made manually or automatically? Describe the process.
  - 1. Automatically: An electronic system creates the assignment list based on firms' risk characteristics and inspectors' area assignments combined with an aging/prioritizing algorithm (e.g. zip code, county/township, past inspection results, consumer complaints, due date, lab results, contract deadlines, etc.)

**TIP:** Think of criteria you would want to use to automate inspection assignments and workload.

- 2. Manually: Assignment list (paper or electronic list) is managed by inspectors and reviewed by their supervisors.
- d. Do you require that inspectors acknowledge receipt of assignment(s)?
  - 1. If yes, for which type of assignments?
  - 2. If yes, how do they acknowledge receipt?

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- e. Do you require that inspectors create a formal itinerary based on their assignment list?
  - 1. What is the time period the itinerary covers?
  - 2. What guidelines are used to create the itinerary?

#### **Core Area #3: Field Work and Inspections**

Purpose: Regulatory program conducts and completes inspectional and investigative work.

- 1. What is required of an inspector before starting an inspection?
  - a. Review of history
    - 1. Review inspection history
    - 2. Review compliance history
    - 3. Review complaint history
    - 4. Review firm's activities/processes
    - 5. Review sample results history
  - b. Are there any formal program policies/procedures outlining requirements (e.g. review at a minimum the last 3 inspection reports)?
  - c. How does an inspector gather or access this information?
- 2. What information might an inspector need to access during the course of an inspection (e.g. guidance on laws and regulations, checklists, special assignment instructions, SOPs, information reviewed in question 1a)?
- 3. What forms does an inspector need to access during the course of an inspection?
- 4. How are inspections conducted? Explain what occurs when conducting an inspection from start to finish.
  - a. Does your program have any formal policies for initiating an inspection at a firm?
  - b. How does an inspector review the firm's activities (including document review)?
  - c. How does an inspector review management/personnel issues (including document review)?
  - d. How does an inspector identify violations and make observations?
  - e. How does an inspector gather, collect, and identify evidence (including samples)?

**TIP:** This information will provide potential contractors and outside parties a good understanding of how an inspection takes place. Often times these parties are unfamiliar with the inspection process.

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#### **Core Area #4: Recording of Findings**

Purpose: Inspector/investigator records findings from or during an inspection or investigation.

- 1. List all forms used to record findings for each type of inspection. For each form:
  - a. In what format is each form provided to the inspector?
    - 1. Paper or hardcopy
    - 2. Electronic document (e.g. Word template or PDF)
    - 3. Electronic application (fillable fields that generate a document)

**TIP:** Are there discrepancies in the form formats needed for an inspection type (e.g., are handwritten and electronic forms both required for an inspection)?

- b. How is each form completed?
  - 1. Handwritten
  - 2. Entered into electronic system (e.g., computer or tablets)

**TIP:** Research how each form is really being used in the field. Are electronic forms being printed and completed by hand?

- 2. How do you record observations?
  - a. Narrative (e.g., free text)
  - b. Checkboxes, select lists, or drop downs that contained pre-defined text or canned comments
  - c. Both
- 3. Are recorded observations referenced to specific Federal, state, or local codes? If so:
  - a. At what level do you cite the references (e.g., section, subsection, paragraph, etc.)?

**TIP:** Does your program have any guidelines for citing references?

- b. Provide an inventory of Federal, state, or local codes that could be referenced.
  - 1. What determines which code you reference?

**TIP:** Think about types of inspections or multiple applicatory regulatory codes covering the same violation.

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c. How does an inspector reference the correct code to the violation observed?

**TIP:** Do they reference hardcopy of law, search electronically, rely on personal knowledge, or have it as part of the form?

#### Core Area #5: Issuance

Purpose: Regulatory authority shares findings with firm or facility and addresses issues of immediate public health concern based on other findings on-site.

- 1. When do you issue the inspection report?
  - a. On site at the time?
  - b. Later date?
- 2. Does an inspection report need supervisory approval prior to issuance?
- 3. Explain the process of issuing an inspection report and any underlying statutory requirements.
- 4. Who does the issuance?
  - a. Field staff
  - b. Supervisor
  - c. Administrative support staff
  - d. Compliance staff
- 5. Is there a requirement for who receives the inspection report?
- 6. In what format is the inspection report issued?
  - a. Paper or hardcopy
  - b. Electronic document (e.g. Word template or PDF)
  - c. Electronic application (fillable fields that generate a document)
  - d. Other
- 7. How is the inspection report delivered to the recipient?
  - a. By hand
  - b. By mail (e.g., USPS, FedEx, etc.)
  - c. Electronic via email
  - d. Posting to a website for download
  - e. Multiple methods (specify)
- 8. Do you document receipt of the inspection report? If so, how?
  - a. Hard copy signature



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- b. Certified mail or delivery signature request
- c. Electronic copy and signature
- d. Electronic verification of delivery
- e. Other

**TIP:** Check on the legality of electronic signatures for your jurisdiction. If they are legal, what's the appropriate process for use?

- 9. How many official reports or copies are generated from one issuance? Where do they go? Who receives them?
- 10. Can your inspectors conduct on-site compliance actions? If so,

**TIP:** This section covers compliance actions taken while on-site. Other compliance actions will be captured in the Compliance and Enforcement Section.

- a. What types of actions can they take?
- b. How do you document the actions being taken?
- c. How do you close, finalize, or resolve the actions taken?
- d. How are these actions currently tracked? What mechanisms are in place?
- e. Do any of these actions trigger/flag another aspect/component of the system?
- f. How do you audit and record that appropriate action was taken?

#### Core Area #6: Review and Approval

Purpose: Formal process for review and approval of an inspection or inspection report.

1. Who might need to have access to inspection materials and what actions might they take?

**TIP:** For instance, who helps determine compliance with law? Which parties, positions, and offices are involved in review and approval of an inspection?

- a. What is their role and position?
- b. How do they access the information?
- c. What review and approval actions do they take with or on the information?

**TIP:** An action could be approval signatures, returning to inspector, filing, forwarding for further review, reviewing, etc.



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#### **Core Area #7: Compliance and Enforcement**

Purpose: To assure that observed violations receive an appropriate response.

**TIP:** While it may not currently be a part of your inspection system, compliance and enforcement is a closely tied process that significantly impacts and is based on the inspection process. Think of other processes, similar to compliance, which might be closely tied to your inspection process.

- 1. What are the different types of actions that can be taken? Identify the tools in your enforcement and compliance toolbox.
- 2. What parties (offices, divisions, people, etc.) would be involved with each action?
- 3. What are the types of violations identified or outlined in state and/or local codes/laws/regulations?
- 4. When a violation occurs, how do you determine the action to take or which enforcement tool to use?

**TIP:** Develop a matrix containing the type of violation and actions/tools used to address the violation.

- 5. What is the process for each action?
  - a. Which of these processes could trigger certain actions automatically?

**TIP:** Think about what compliance activities or actions an IT system could automatically generate upon review of inspection information or related material (e.g., licensing, lab results).

- 6. What documentation do you need to support each action?
  - a. How is the documentation completed?
- 7. Do any of these actions trigger/flag another aspect/component of this system or any other systems?

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#### **Core Area #8: Record Creation and Retention**

Purpose: Enter, store, and archive records from investigative or inspectional work.

1. What are the different types of records your program creates?

**TIP:** A record could be something like an inspection report, enforcement letter, sample collection report, or lab analysis report.

- a. What data elements are captured in each type of record?
- b. Are there any relationships between these records?
- c. Is this different based upon license type?
- 2. What other regulatory information is provided to your program by other regulatory authorities or 3<sup>rd</sup> parties that might create a record or contribute a data element?
- 3. For each record, outline the procedure used to create and retain the information.
  - a. Do you have laws or regulations overseeing this?
  - b. Who handles this?
  - c. Which records, when stored, need to be related back to an establishment?
- 4. How do you correlate all relevant documents and supporting materials (floor plans, photographs, samples) associated with an inspection?

**TIP:** An example of this could be the use of an establishment name or ID and a date.

- a. Which supporting materials, when stored, need to be related back to a specific inspection?
- b. What are your procedures to establish and maintain chain of custody?

**TIP:** Additionally, consider ways an electronic system could be used to implement or strengthen chain of custody procedures (e.g., single sign-on, role-based access of permissions, change log, etc.).

- 5. How do you ensure data integrity?
  - a. Are there records where edits can be made?
    - 1. If so, how are these edits tracked?
    - 2. If not, how do you ensure they are not editable?
  - b. What constitutes an official record?
  - c. Are there any laws or regulations that govern data integrity?
  - d. What are your standard operating procedures or policies for data integrity?

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#### **Core Area #9: Data Management**

Purpose: Manage inspection and establishment records to review and analyze internally or share externally.

- 1. Is there an office or person in your organization who can advise you on the relevant privacy laws affecting your program?
- 2. What laws, regulations, policies, or authorities govern your collection and use of Personal Identifiable Data (PII)?
  - a. How does your program define PII?
  - b. What PII does your program regularly collect?
  - c. How is the PII maintained?
    - 1. What methods are used to restrict access to PII in accordance with applicable laws and policies?
    - 2. How is PII destroyed when it is no longer needed?
  - d. Does your program use a contractor to collect and/or maintain PII?
    - 1. If so, what privacy laws apply to the contractor, vendor, or service provider?
- 3. Does your program have a data breach or privacy incident reporting plan?
  - a. How does your program define "privacy incident" or "breach"?
  - b. To whom and what office must staff report a privacy incident?
  - c. Are you required to report incidents to federal, state or local authorities?
- 4. Does your program employ methods to provide individuals any notice or obtain any required consent when collecting PII?
- 5. How long must data be stored?
  - a. What is your program's document retention schedule?
  - b. How do you destroy records?
    - 1. What is the policy for destroying records?
- 6. How does your program handle Freedom of Information Act (FOIA) requests?
  - a. What are the guidelines for submitting and fulfilling a request?
  - b. What is the format and mechanism for the request and response?
  - c. What are guidelines for length of time to fulfill request?
  - d. What are your procedures for redacting information?
  - e. Are certain records or data exempt from FOIA requests?
- 7. How do you analyze your data?
  - a. What types of analysis help you review and analyze your program (e.g., inspection records to firm history, trends of issues by violation, by risk category, by product type, etc.)?



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- 1. How does your program or department measure "efficiency?"
- 2. How does your program or department measure "effectiveness?"
- b. What types of analysis are based upon regulatory requirements?
  - 1. What particular data fields or key elements are included in each analysis?
- c. Are trend analyses conducted? (looking at change over time)
  - 1. What particular data fields or key elements are included in the trend analysis?

**TIP:** Analysis is the process; a report is a potential outcome of conducting an analysis. There are different types of analysis, such as trend analysis.

**TIP:** If you are completing the tool a second time (i.e., answering the questions in context of where your agency "wants to be"), think about how you would like to analyze the data and how you would structure the data in order to run the analysis. Professional help may be needed to assist with the process! Academia, universities with a computer science or library sciences (information sciences) program, might offer a good and affordable resource.

- 8. Who outside your division/agency commonly asks for reports?
  - a. Who are the reports for?
  - b. What types of information are included in the reports?
  - c. What are your regulatory requirements?
  - d. How often are the reports run?
  - e. What triggers this information to be shared?

**TIP:** A trigger could be rules, public request, regulatory partnerships, divisions/departments intra and inter-state needs, etc.

- f. Why are the reports run?
- g. In what format is it provided (e.g., Word, Excel, etc.)?

**TIP:** These reports could be used to make program decisions (resource allocation) or enforcement decisions (warning letters). Do not forget that the reports you run could be reoccurring or required reports (canned reports), or ad hoc reports you might want to have as a result of a specific analysis.



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**TIP:** It might be a good idea to rank the importance of each report (based on its need and frequency) in order to ensure that reporting needs are fully met while minimizing costs. Enabling a large degree of ad hoc reporting can become expensive to develop, but provide a larger degree of flexibility. Canned reporting tends to be less expensive, but limits your ability to provide customizations.

**TIP:** If you are completing the tool a second time (e.g., answering the questions in context of where your agency "wants to be"), consider what types of internal reports you would like to be able to run. Include all of the sub-questions (8a-g) in your answer.

- 9. What information is protected from public information requests?
- 10. What are your security, data access, and data sharing policies?
  - a. For internal users?
  - b. For external users?
  - c. Are there types of data or reports that need different levels of security?
- 11. What is your continuity of business policy?
  - a. Are there off-site backup needs or requirements?